BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Strensiq™

Policy Number: 9.312
Version Number: 2.0
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Strensiq™(asfotase alfa)

The Plan may authorize coverage of the above product(s) for members meeting the following criteria:

Covered Use	All FDA approved indication unless otherwise excluded.
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of perinatal/infantile-onset or juvenile-onset hypophosphatasia (HPP); ***AND*** 2. Documented history of clinical manifestations consistent with HPP (e.g. skeletal abnormalities, respiratory problems, hypercalcemia, seizures); ***AND*** 3. Documentation of one of the following:

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	a. Tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation; ***OR*** b. Serum alkaline phosphatase (ALP) level below the age-adjusted normal range AND plasma pyridoxal-5-'phosphate (PLP) above the upper limit of normal at baseline ; ***AND*** 4. The request is for dosing regimen of 2 mg/kg three times per week; ***AND*** 5. Member's current weight is provided; ***AND*** 6. For children weighing less than 40 kg: the 80 mg/0.8 mL concentration vial will not be used
Age Restrictions	None
Prescriber Restriction	Prescribed by an endocrinologist or other provider who specializes in the treatment of perinatal/infantile- or juvenile-onset HPP
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: 1. Initial criteria are met; ***AND*** 2. There has been a clinically significant improvement in the member's condition without adverse effects.

Clinical Background Information and References

1. Mornet, Etienne. "Hypophosphatasia." Orphanet Journal of Rare Diseases 2 (2007): 40. PMC. Web. 29 June 2016.
2. Strensiq™ (asoftase alfa). Prescribing information. Alexion Pharmaceuticals, Inc. Cheshire, CT. October 2015.
3. Strensiq drug information. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on March 28, 2019.)

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**

Policy Revisions History			
12/1/2020	9.068 Strensiq Policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	P&T annual review. Simplified diagnosis language. Changed documentation requirement to be gene mutation OR abnormal labs, not both.	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.